

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

## Complete If Known

Application Number	10/561,343
Filing Date	December 20, 2005
First Named Inventor	KRUPKA
An Unit	
Examiner Name	
Attorney Docket Number	05552.1484

## U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials	Cite No.	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-			

Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>4</sup>
		Country Code <sup>3</sup> Number <sup>1</sup> Kind Code <sup>4</sup> (if known)				
Sh		WO-02/079217 A1	10-10-2002	ABBOTT LABORATORIES		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>5</sup>
Sh		LEE; "HEPATITIS B VIRUS INFECTION", The New England Journal of Medicine, Vol. 337, No. 24, pages 1733-1745, (1997)	
Sh		TIOLLAIS et al.; "THE HEPATITIS B VIRUS", Nature, Vol. 317, pages 489-495, (1985)	
Sh		GERLICH et al.; "FUNCTIONS OF HEPATITIS B VIRUS PROTEINS AND VIRUS ASSEMBLY", Viral Hepatitis and Liver Disease, pages 121-134, (1991)	
Sh		BLUM; "VARIANTS OF HEPATITIS B, C AND D VIRUSES: MOLECULAR BIOLOGY AND CLINICAL SIGNIFICANCE", Digestion, Vol. 58, pages 85-95, (1995)	
Sh		OKAMOTO et al.; "GENOMIC HETEROGENEITY OF HEPATITIS B VIRUS IN A 54-YEAR-OLD WOMAN WHO CONTRACTED THE INFECTION THROUGH MATERNO-FETAL TRANSMISSION", Japan. J. Exp. Med., Vol. 57, No. 4, pages 231-236, (1987)	
Sh		CARMAN et al.; "VIRAL GENETIC VARIATION: HEPATITIS B VIRUS AS A CLINICAL EXAMPLE", The Lancet, Vol. 341, pages 349-353, (1993)	
Sh		COUTROUCE et al.; "BIBLIOTHECA HAEMATOLOGICA No. 42", pages 1-19, (1976)	
Sh		NORDER et al.; "MOLECULAR BASIS OF HEPATITIS B VIRUS SEROTYPE VARIATIONS WITHIN THE FOUR MAJOR SUBTYPES", Journal of General Virology, Vol. 73, pages 3141-3145, (1992)	
Sh		NORDER et al.; "COMPLETE GENOMES, PHYLOGENETIC RELATEDNESS, AND STRUCTURAL PROTEINS OF SIX STRAINS OF THE HEPATITIS B VIRUS, FOUR OF WHICH REPRESENT TWO NEW GENOTYPES", Virology, Vol. 198, pages 489-503, (1994)	
Sh		COOREMAN et al.; "CHARACTERIZATION OF THE REACTIVITY PATTERN OF MURINE MONOCLONAL ANTIBODIES AGAINST WILD-TYPE HEPATITIS B SURFACE ANTIGEN TO G145R AND OTHER NATURALLY OCCURRING "a" LOOP ESCAPE MUTATIONS", Hepatology, Vol. 30, No. 5, pages 1287- 1292, (1999)	
Sh		TERRAULT et al.; "INCIDENCE AND CLINICAL CONSEQUENCES OF SURFACE AND POLYMERASE GENE MUTATIONS IN LIVER TRANSPLANT RECIPIENTS ON HEPATITIS B IMMUNOGLOBULIN", Hepatology, Vol. 28, No. 2, pages 555-561, (1998)	
Sh		TILLMAN et al.; "MUTATIONAL PATTERN OF HEPATITIS B VIRUS ON SEQUENTIAL THERAPY WITH FAMCICLOVIR AND LAMIVUDINE IN PATIENTS WITH HEPATITIS B VIRUS REINFECTION OCCURRING UNDER HBIG IMMUNOGLOBULIN AFTER LIVER TRANSPLANTATION", Hepatology, Vol. 30, No. 1, pages 244-256, (1999)	
Sh		HUNT et al.; "CLINICAL RELEVANCE OF HEPATITIS B VIRAL MUTATIONS", Hepatology, Vol. 31, No. 5, pages 1037-1044, (2000)	
Sh		COOREMAN et al.; "VACCINE-AND HEPATITIS B IMMUNE GLOBULIN-INDUCED ESCAPE MUTATIONS OF HEPATITIS B VIRUS SURFACE ANTIGEN", J. Biomed. Sci., Vol. 8, pages 237-247, (2001)	
Sh		PETERSON et al.; "ANTIGENIC STRUCTURE OF HEPATITIS B SURFACE ANTIGEN: IDENTIFICATION OF THE "a" SUBTYPE DETERMINANT BY CHEMICAL MODIFICATION AND USE OF MONOCLONAL ANTIBODIES", The Journal of Immunology, Vol. 132, No. 2, pages 920-927, (1984)	

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Attorney Docket Number 05552.1464

### NON PATENT LITERATURE DOCUMENTS

86	JILG; "NOVEL HEPATITIS B VACCINES"; Vaccine, Vol. 16, pages 565-568, (1998)
8h	CARMAN et al.; "HEPATITIS B VIRUS ENVELOPE VARIATION AFTER TRANSPLANTATION WITH AND WITHOUT HEPATITIS B IMMUNE GLOBULIN PROPHYLAXIS"; Hepatology, Vol. 24, No. 3, pages 489-493, (1996)
5h	MÜLLER et al.; "LIVER TRANSPLANTATION IN HBsAg CARRIERS [PREVENTION OF HEPATITIS B VIRUS (HBV) RECURRENCE BY PASSIVE IMMUNIZATION]; Journal of Hepatology, Vol. 13, pages 90-96, (1991)
5h	SAMUEL et al.; "LIVER TRANSPLANTATION IN EUROPEAN PATIENTS WITH THE HEPATITIS B SURFACE ANTIGEN"; The New England Journal of Medicine, Vol. 329, No. 25, pages 1842-1847, (1993)
5h	BRIND et al.; "EVIDENCE FOR SELECTION OF HEPATITIS B MUTANTS AFTER LIVER TRANSPLANTATION THROUGH PERIPHERAL BLOOD MONONUCLEAR CELL INFECTION"; Journal of Hepatology, Vol. 26, pages 228-235, (1997)
5h	FISHER et al.; "HEPATITIS B VIRUS VARIANT'S ASSOCIATED WITH CLINICALLY SEVERE RECURRENCE AFTER LIVER TRANSPLANTATION"; Transplantation Proceedings, Vol. 31, pages 492-493, (1999)
5h	GHANY et al.; "HEPATITIS B VIRUS S MUTANT IN LIVER TRANSPLANT RECIPIENTS WHO WERE REINFECTION DESPITE HEPATITIS B IMMUNE GLOBULIN PROPHYLAXIS"; Hepatology, Vol. 27, No. 1, pages 213-222, (1998)
5h	PROTZER-KNOLLE et al.; "HEPATITIS B VIRUS WITH ANTIGENICALLY ALTERED HEPATITIS B SURFACE ANTIGEN IS SELECTED BY HIGH-DOSE HEPATITIS B IMMUNE GLOBULIN AFTER LIVER TRANSPLANTATION"; Hepatology, Vol. 27, No. 1, pages 254-263, (1998)
5h	CARMAN et al.; "GENETIC VARIATION IN HEPATITIS B VIRUS"; Gastroenterology, Vol. 102, No. 2, pages 711-719, (1992)
5h	CARMAN; "THE CLINICAL SIGNIFICANCE OF SURFACE ANTIGEN VARIANTS OF HEPATITIS B VIRUS"; Journal of Viral Hepatitis, Vol. 4, Suppl. 1, pages 11-20, (1997)
5h	SWENSON et al.; "DETERMINATION OF HBsAg SUBTYPES IN DIFFERENT HIGH RISK POPULATIONS USING MONOCLONAL ANTIBODIES"; Journal of Virological Methods, Vol. 33, pages 27-38, (1991)
5h	BLITZ et al.; "ANTIGENIC DIVERSITY OF HEPATITIS B VIRUS STRAINS OF GENOTYPE F IN AMERICANS AND OTHER POPULATION GROUPS FROM VENEZUELA"; Journal of Clinical Microbiology, Vol. 38, No. 3, pages 548-551, (1998)
5h	ASHTON-RICKARDT et al.; "MUTATIONS THAT CHANGE THE IMMUNOLOGICAL SUBTYPE OF HEPATITIS B VIRUS SURFACE ANTIGEN AND DISTINGUISH BETWEEN ANTIGENIC AND IMMUNOGENIC DETERMINATION"; Journal of Medical Virology, Vol. 29, pages 204-214, (1989)
5h	OHBA et al.; "RELATIONSHIPS BETWEEN SEROTYPES AND GENOTYPES OF HEPATITIS B VIRUS: GENETIC CLASSIFICATION OF HBV BY USE OF SURFACE GENES"; Virus Research, Vol. 39, pages 25-34, (1995)
5h	CARMAN et al.; "FULMINANT REACTIVATION OF HEPATITIS B DUE TO ENVELOPE PROTEIN MUTANT THAT ESCAPED DETECTION BY MONOCLONAL HBsAg ELISA"; The Lancet, Vol. 345, pages 1406-1407, (1995)
5h	OKAMOTO et al.; "MUTATIONS WITHIN THE S GENE OF HEPATITIS B VIRUS TRANSMITTED FROM MOTHERS TO BABIES IMMUNIZED WITH HEPATITIS B IMMUNE GLOBULIN AND VACCINE"; Pediatric Research, Vol. 32, No. 3, pages 284-288, (1992)
5h	ZHANG et al.; "INCREASING HETEROGENEITY OF THE 'a' DETERMINANT OF HBsAg FOUND IN THE PRESUMED LATE PHASE OF CHRONIC HEPATITIS B VIRUS INFECTION"; Scand. J. Infect. Dis. Vol. 28, pages 9-15, (1996)
5h	ZUCKERMAN et al.; "MUTATIONS IN S REGION OF HEPATITIS B VIRUS"; The Lancet, Vol. 343, pages 737-738, (1994)
5h	SMITH et al.; "COMPARISON OF BIOSEQUENCES"; Advances in Applied Mathematics, Vol. 2, pages 482-489, (1981)
5h	SCHWARTZ et al.; "MATRICES FOR DETECTING DISTANT RELATIONSHIPS"; Atlas of Protein Sequence and Structure, pages 353-358, (1976)
5h	GRIBSKOV et al.; "SIGMA FACTORS FROM E. COLI, B. SUBTILIS, PHAGE SP01, AND PHAGE T4 ARE HOMOLOGOUS PROTEINS"; Nucleic Acids Research, Vol. 14, No. 16, pages 6745-6763, (1986)
5h	SAMSBROOK et al.; "MOLECULAR CLONING: A LABORATORY MANUAL, 2 <sup>ND</sup> EDITION"; Cold Spring Harbor Laboratory Press, New York, pages i-xcvi, (1989)
5h	AUSUBEL et al.; "A COMPENDIUM OF METHODS FROM CURRENT PROTOCOLS IN MOLECULAR BIOLOGY"; Short Protocols in Molecular Biology, 2 <sup>ND</sup> Edition, John Wiley & Sons, pages iii-xvii, (1992)
5h	KOEHLER et al.; "CONTINUOUS CULTURES OF FUSED CELLS SECRETING ANTIBODY OF PREDEFINED SPECIFICITY"; Nature, Vol. 256, pages 495-497, (1975)

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Sh	MIMMS et al.; "DISCRIMINATION OF HEPATITIS B VIRUS (HBV) SUBTYPES USING MONOCLONAL ANTIBODIES TO THE PreS1 AND PreS2 DOMAINS OF THE VIRAL ENVELOPE"; Virology, Vol. 176, Pages 604-619, (1990)	
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Examiner Signature	Sharon Hunt	Date Considered	Dec 21, 2006
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